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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,967	04/07/2000	MATS WAHLGREN	45300-59676	4801

466 7590 06/13/2003

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EXAMINER

MINNIFIELD, NITA M

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/13/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,967

Applicant(s)

WAHLGREN ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,14,17,21,24,33-35,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13,14,17,21,24,33-35,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 21
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed April 1, 2003 is acknowledged and has been entered. Claims 15 and 36 have been canceled. Claims 13, 14, 33, 35 and 38 have been amended. Claims 13, 14, 17, 21, 24, 33-35, 37 and 38 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 10 for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
4. Claims 13, 17, 21, 24, 33, 35, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13, 17, 21, 24, 33, 35, 37 and 38 are vague and indefinite in the recitation of "capable of"; it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Claims 17 and 37 are vague and indefinite in the recitation of a molecular weight; how is the molecular weight determined?

5. Claim 34 is objected to because of the following informalities: claim 34 depends from canceled claim 22. Claim 38 should read --an adjuvant--, not "and adjuvant". Appropriate correction is required.

6. Claim 14 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The product, as claimed, has the same characteristics and utility as that found in nature. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations which would distinguish the characteristics and utility of applicant's product as enabled in the specification from the utility of the product as it exists in nature. It is further suggested that such limitation include the terminology "essentially purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what applicant's protein is "free of" relative to the natural source, which imparts a distinct utility to the claimed product. For relevant case law see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

7. The rejection of claims 24, 33, 34 and 38 under 35 U.S.C. § 112, first paragraph, because the specification is not enabled for the scope of enablement for a pharmaceutical, vaccine or medicament comprising the polypeptide or any amino-terminal part of the polypeptide of SEQ ID NO: 1 is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims

24, 33, 34 and 38 under this statutory provision, as set forth in paragraph 6 of the last Office action. Applicants' arguments filed April 1, 2003, have been fully considered but they are not deemed to be persuasive.

Applicants have asserted that they "...believe that due to constant human immune pressure, PfEMP1 molecules are variable in size and sequence. However, an increasing pool of data indicates that only a few species of PfEMP1 can cause severe episodes like cerebral or placental malaria. Interestingly, these PfEMP1s seem to be commonly recognized by antibodies from individuals who are resistant to severe malaria. Thus, it's likely that cerebral malaria or placental malaria can be prevented through immunizations with one or a few species of PfEMP1." (Amendment, pp.10-11). It is noted that Applicants have not provided any evidence of this belief.

Applicants refer to Carlson et al, 1999 and Chen et al, 2003 to indicate that the DBL-1 domain is the most conserved domain of the PfEMP1 domain. However, these references have not been provided. No citation has been provided.

Applicants have asserted that they have discovered that immune-antibodies generated by a vaccination with recombinant PfEMP1-DBL-1 constructs of FCR3S1.2 recognize native PfEMP1 on a live infected red blood cell surface, disrupt preformed *P. falciparum* rosettes and hinder the adhesion of infected erythrocytes in an animal model, (newly developed rat model, Chen et al, 2003). However, it is noted that the specification shows no animal model correlation to data that the polypeptide in the form of a composition (vaccine, pharmaceutical or medicament) can function in that capacity. Again, the Chen et al, 2003 reference

has not been provided. Further, any data regarding the enablement of the claimed invention should be provided in the form of a declaration.

8. The rejection of claims 13, 14, 17, 21, 14, 33-35, 37 and 38 under 35 U.S.C. § 112, first paragraph, because the specification is not enabled for the scope of enablement of a polypeptide comprising any part of SEQ ID NO: 1 is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 13-15, 17, 21, 24 and 33-38 under this statutory provision, as set forth in paragraph 7 of the last Office action. Applicants' arguments filed April 1, 2003, have been fully considered but they are not deemed to be persuasive.

It is noted that Applicants have not responded to this rejection.

9. The rejection of claims 13, 14, 24, 33-35, 37 and 38 under 35 U.S.C. § 102(b) as anticipated by Helmby et al, 1993 (Infection and Immunity, 61/1284-288) is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 13-15, 24 and 33-38 under this statutory provision, as set forth in paragraph 9 of the last Office action. Applicants' arguments filed April 1, 2003 have been fully considered but they are not deemed to be persuasive.

Applicants have asserted that the prior art discloses proteins termed rosettings, but that proteins are not involved in resetting referring to Fernandez et al, 1999. However, this limitation is not set forth in the claims. Applicants have asserted that the polypeptides have a molecular size of less than 200 kD and that this is a size quite distinct from the known PfEMP1 antigens. However, the molecular weight of the polypeptide is not recited in the claims. Further, the claims recite that the polypeptide comprises an amino-terminal part of the

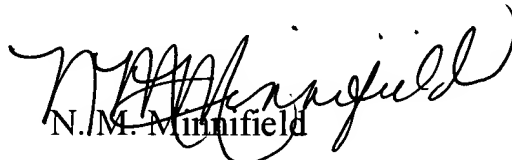
sequence according to SEQ ID NO: 1; the limits of the amino-terminal part of the sequence according to SEQ ID NO: 1 have not been defined. Therefore, Helmby et al would appear to disclose the claimed invention.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



N. M. Minnifield

Primary Examiner

Art Unit 1645

NMM

June 6, 2003